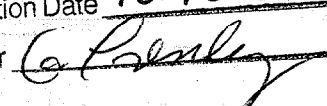


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Dermatologic and Ophthalmic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA'S regulatory issues.

Date and Time: The meeting will be held on November 4, 2002, from 8:30 a.m. to 5:30 p.m. and November 5, 2002, from 8 a.m. to 1 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, e-mail: SomersK@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting.

Agenda: On both the days, committee will make recommendations for the development of a proposed draft guidance concerning the development of

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products for mild to moderate acne vulgaris. Issues to be considered include:

(1) The evidence for effectiveness; (2) appropriate outcome measures and their analyses; (3) possible acceptable indications such as inflammatory, noninflammatory or just mild to moderate acne vulgaris; and (4) means for conveying evidence for effectiveness in the label to enhance its usefulness for clinicians and patients. Time will be included in the agenda for the pharmaceutical industry to present their views on the development of the draft guidance. Please register to present (see *Contact Person*) by October 18, 2002.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 18, 2002. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m. on November 4, 2002, and between approximately 8:15 a.m. and 8:45 a.m. on November 5, 2002. Time allotted for each presentation may be limited. If you wish to make a brief statement during the open public hearing, please contact the Executive Secretary (see *Contact Person*), by October 18, 2002.

You will be asked to submit a brief summary of your planned statement and provide information on how we may contact you before the meeting.

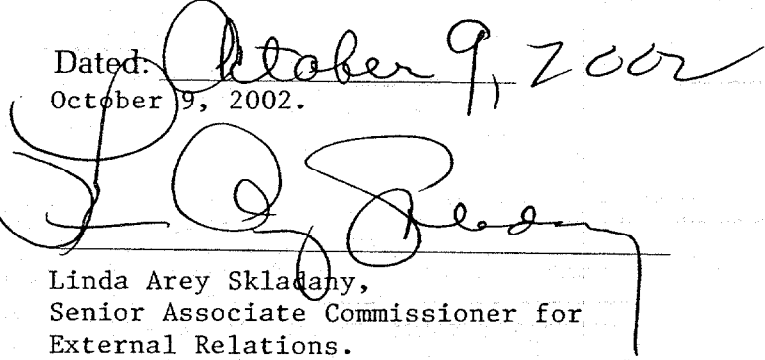
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Karen Templeton-Somers at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act
(5 U.S.C. app. 2).

Dated:

October 9, 2002.


Linda Arey Skladany,
Senior Associate Commissioner for
External Relations.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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